DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

P960040

Date JUL 18 1997

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Guidant Corporation, VENTAK® AV AICD™ Model 1810/Model 1815 Automatic Implantable Cardioverter Defibrillator (AICD™) with the Model 2833 Software Application - ACTION

To The Director, CDRH
ORA ________

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D., M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date ____________________

Prepared by Carole C. Carey, CDRH, HFZ-450, July 3, 1997, 443-8609

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

Food and Drug Administration

[DOCKET NO. __________]

Guidant Corp.; Premarket Approval OF VENTAK® AV AICD™ Model 1810/Model 1815 Automatic Implantable Cardioverter Defibrillator (AICD™) with the Model 2833 Software Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Guidant Corp., St. Paul, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of VENTAK® AV™ AICD System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant by letter of July 18, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFZ-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Carole C. Carey,

Center for Devices and Radiological Health (HFZ-450),

Food and Drug Administration,

9200 Corporate Boulevard,

Rockville, Maryland 20850,

301-443-8609.

SUPPLEMENTARY INFORMATION: On August 20, 1996, Guidant Corp., St. Paul, MN 55112-5798, submitted to CDRH an application for premarket approval of VENTAK® AV AICD™ Model 1810/Model 1815 Automatic Implantable Cardioverter Defibrillator (AICD™) with the Model 2833 Software Application which consists of the following: Model 1810/Model 1815 pulse generator and Model 2833 Software Application to be used with commercially available Cardiac Pacemakers, Inc., Programmer/Recorder/Monitor (PRM). The device is a multiprogrammable automatic, implantable dual-chamber pacemaker and cardioverter defibrillator, and is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations: survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia; recurrent, poorly tolerated sustained ventricular tachycardia (VT); prior myocardial infarction, left ventricular ejection fraction of ≤ 35 percent, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic have not been studied. *NOTE: The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.* The VENTAK AV AICD pulse generator is not intended for use solely as a primary bradycardia support device.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On July 18, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act, authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: ______________________.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 1997

Ms. Janet Cowan, RAC
Senior Regulatory Affairs Assaociate
Guidant Corporation
Cardiac Pacemakers (CPI)
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798

Re: P960040
VENTAK® AV™ AICD™ Model 1810/Model 1815 Automatic Implantable Cardioverter Defibrillator (AICD™) with the Model 2833 Software Application
Filed: August 20, 1996
Amended: September 30, November14, and December 9, 1996, June 4, July 1, July 15, and July 17, 1997

Dear Ms. Cowan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the VENTAK® AV™ AICD™ Model 1810/Model 1815 Automatic Implantable Cardioverter Defibrillator (AICD™) with the Model 2833 Software Application. This device is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations: survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia; recurrent, poorly tolerated sustained ventricular tachycardia (VT); prior myocardial infarction, left ventricular ejection fraction of ≤ 35 percent, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic have not been studied. *NOTE: The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.* The VENTAK AV AICD pulse generator is not intended for use solely as a primary bradycardia support device.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval for Implantable Defibrillators and Programmers" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for this device has been established and approved at 1 year from the 'battery attach' date. The storage temperature is between 0° - 50°C (32° - 122°F)..

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

In addition under section 522(a) of the act, manufacturers of certain types of devices identified by the act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under section 522(a)(1)(A) the above noted device as requiring postmarket surveillance.

Upon approval and within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you will be required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is enclosed.

At that time you should submit five (5) copies to:

Postmarket Studies Document Center
1350 Piccard Drive (HFZ-544)
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. Do not undertake a postmarket surveillance study without an FDA approved protocol.

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol, will be considered violations of section 522.

In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the act (21 U.S.C. 331(q)(1)(C)). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties or other FDA enforcement actions including (but not limited to) withdrawal of your PMA.

If you have any questions concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch, at (301) 594-0639.

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences.

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR § 821.20(b) and the devices that FDA has designated for tracking at 21 CFR § 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)).

If you have questions concerning this approval order, please contact Carole C. Carey at (301) 443-8609.

Sincerely yours,

Susan Alpert

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Summary of Safety and Effectiveness Data

VENTAK AV AICD System

P960040

Notice of Approval Date: July 18, 1997

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation

TABLE OF CONTENTS

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

Device Generic Name:	Implantable Dual Chamber Pacemaker and Cardioverter Defibrillator Pulse Generator and Program Software
Device Trade Name:	VENTAK®AV™ Model 1810/Model 1815 Automatic Implantable Cardioverter Defibrillator (AICD™) with the Model 2833 Software Application
Applicant's Name	GUIDANT Corporation-Cardiac Pacemakers (CPI) 4100 Hamline Ave. North St. Paul, MN 55112-5798
Pre-market Approval (PMA) Application Number:	P960040
Date of Notice of Approval to Applicant:	July 18, 1997

II. INDICATIONS FOR USE

The VENTAK AV Model 1810/1815 AICD system is indicated for use in patients who are at high risk of sudden death due to ventricular arrhythmias and who have experienced one of the following situations: survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyarrhythmia; or recurrent, poorly tolerated sustained ventricular tachycardia (VT); or a prior myocardial infarction, left ventricular ejection fraction of $\leq$ 35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic have not been studied. *NOTE: The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.* The VENTAK AV AICD System is not intended for use solely as a primary bradycardia support device.

III. DEVICE DESCRIPTION

The VENTAK AV AICD is a multiprogrammable, automatic, implantable cardioverter-defibrillator with bidirectional telemetry. As a multifunctional electrical device (defibrillator and dual chamber pacemaker, DDD), it is designed to provide defibrillation therapy (biphasic and monophasic shocks) as well as antitachycardia pacing (ATP) and dual chamber bradycardia therapy (atrial and ventricular pacing).

The pulse generator (Model 1810 or Model 1815), along with compatible commercially available pace/sense leads and cardioversion/defibrillation leads constitutes the implantable portion of the AICD system. Also, the pulse generator case acts as a defibrillating electrode. The lead systems for the VENTAK AV AICD pulse generator are implanted using either transthoracic or transvenous techniques. The CPI Programmer/ Recorder/Monitor (PRM), the Model 2833 Software Application, and an accessory telemetry wand constitutes the external portion of the AICD.

A. The VENTAK AV Pulse Generator

The VENTAK AV pulse generator consists of Models 1810 and 1815 which have the following approximate weight, volume, external dimensions, and connector size (Table 1):

Table 1. VENTAK AV Pulse Generator Physical Characteristics

VENTAK AV Models	Weight	Volume	Dimensions	Connector Size
1810	150 grams	79 cc	85 mm x 64 mm x 17.5 mm	3.2 mm (DF-1) shocking ports (2 ports) 3.2 mm (IS-1) ventricular pace/sense port (1 port) 3.2 mm (IS-1) atrial port (1 port)
1815	158 grams	85 cc	96 mm x 64 mm x 17.5 mm	6.1/4.75 mm shocking port (2 ports) 4.75 mm ventricular pace/sense port (1 port) 3.2 mm (IS-1) atrial pace/sense port (1 port)

The external case of the pulse generator is constructed of titanium with a premolded header top made of a polyurethane lead connector assembly. The inner assembly (hermetically sealed in the titanium case) contains an inner structure of discrete electrical components, interconnected hybrid circuit assemblies (one analog and one digital), batteries (two lithium-silver vanadium oxide), two high-voltage capacitors, a high power output module, and a telemetry coil.

Sensing and Detection. Rate is the primary detection criteria with a programmable range of 90–250 bpm in conjunction with a programmed duration (1–60 seconds). The VENTAK AV uses automatic gain control circuitry (AGC) in the atrium and in the ventricle to sense tachyarrhythmias and bradyarrhythmias. The maximum sensitivity to sense tachyarrhythmias and bradyarrythmias is 0.182 mV (ventricular) and 0.182 mV (atrial). When a pace pulse is delivered, the AGC sets the amplifier sensitivity at a fixed level during the paced refractory.

Each arrhythmia is classified into a programmed rate zone defined by an upper and lower heart rate boundary. The pulse generator can be programmed as a one-zone, two-zone, or a three-zone configuration. Like its predecessors, the VENTAK AV pulse generator also provides a series of detection enhancements: *Onset*, *Stability*, and *Sustained Rate Duration* (SRD). However, unlike any commercially available implantable cardioverter-defibrillator, the VENTAK AV uses atrial rate information obtained from the atrial lead along with the detection enhancement features. Detection enhancements are designed to increase the specificity of the rate detection algorithm and can be used to distinguish between different types of arrhythmias within a single rate zone. The purpose of atrial rate detection is to withhold therapy in the event that the underlying cause of a moderately high ventricular rate is due to ventricular response to fibrillation in the atrium.

If the ventricular rhythm is unstable and the atrial rate is greater than the *AFIB* rate threshold, the ventricular rhythm is declared to be atrial fibrillation. Therapy will be withheld until the atrial rate drops below the *AFIB* rate threshold, the ventricular rhythm becomes stable, or the *Sustained Rate Duration* timer expires. The V Rate > A Rate (Ventricular rate greater than atrial rate) feature can also be programmed to bypass *Onset* and/or *Stability* as inhibitors and the device will initiate therapy in the event that the ventricular rate is greater than the atrial rate.

Therapy. A tachyarrhythmia that falls into the programmed heart rate range (VT-1, VT, or VF) will be treated by the therapy programmed for that range. The initial therapy is invoked when the criteria for detection is satisfied to treat an arrhythmia in the selected regimen. Tachyarrhythmia therapy which includes one or two ATP schemes and up to five shocks occur in the ventricle only. Defibrillation or cardioversion shocks range from 0.1 to 29 joules (J) delivered energy in which only the first two shock energies in each zone are programmable; the remaining three shocks are nonprogrammable at 29 J. The type and polarity of the shock waveform are also programmable. If multiple therapies are required, the hierarchy of therapy is a progression from pacing to shock, with shock energies always equal to or greater than the previous shocks within the same episode. A redetection algorithm determines whether the device has crossed zone boundaries and will deliver the programmed therapy in the new zone. Following shock therapy, converted rhythms are analyzed as to the need for bradycardia treatment and provide high output brady pace pulses, if programmed. The VENTAK AV also provides standard DDD pacing for the treatment of bradycardia.

Memory and Diagnostics. Programmed parameters as well as model number, serial number, episode count, shock lead impedance, shocks delivered and diverted, and battery status are stored in the pulse generator's memory. The VENTAK AV also stores patient information surrounding each therapy episode including (1) the date and elapsed time; (2) attempt data that includes the number of therapy attempts; (3) shock energy level and shocking lead impedance of each attempt; (4) the detected heart rate; (5) the presence of stored electrograms; and, (6) reconfirmation results. Therapy detail of up to 69 single attempt episodes and up to 16 minutes of electrograms surrounding the most recent episodes can be stored. The VENTAK AV pulse generator provides the following diagnostic and optional features: (1) real-time electrogram and event markers which assist in evaluating system response; (2) non-invasive methods for inducing arrhythmias; (3) automatic battery voltage evaluation every 24 hours; (4) automatic capacitor reformation every 90 days; (5) pacing lead impedance, which can be used as a relative indicator of lead status over time; (6) battery status indicator displayed as one of three levels: Beginning of Life (BOL), Elective Replacement Indicator (ERI), and End of Life (EOL); (7) programmable audible tones (beeper function) which can be used to assist with system evaluation such as pulse generator battery status, capacitor charging, and ventricular rate sensing; (8) magnet control which can be programmed OFF to ensure the tachy mode will not be changed in the presence of a magnetic field, or programmed ON to allow the tachy mode of the pulse generator to be changed from OFF(inactive) or MONITOR ONLY mode to MONITOR AND THERAPY mode or from MONITOR AND THERAPY mode to OFF mode. The magnet can also divert or inhibit therapy, and activate the beeper.

B. The Programming System and Model 2833 Software Application

A commercially available programming system (Model 2901 or 2950 PRM and its accessories) provides communication between the physician and the pulse generator via bidirectional radio frequency (RF) telemetry. This allows identification of the implanted pulse generator. The Model 2833 Software Application contains the software code specifically required to interface with and program only the CPI VENTAK AV Models 1810 and 1815 pulse generators. The software allows the user to interrogate, program, and command certain functions; such as, parameter programming codes, intracardiac electrograms, and event markers.

IV. CONTRAINDICATIONS

The use of the VENTAK AV pulse generator is contraindicated in: (1) patients whose ventricular tachyarrhythmias may have reversible cause (such as digitalis intoxication, electrolyte imbalance, hypoxia, or sepsis), or whose ventricular tachyarrhythmias have a transient cause (such as acute myocardial infarction, electrocution, or drowning, and (2) patients who have a unipolar pacemaker. *Note: If a separate pacemaker is desired, a dedicated bipolar pacemaker is recommended.*

DDD and VDD modes are contraindicated as follows: (1) in patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which may trigger ventricular pacing, and (2) in the presence of slow retrograde conduction that induces pacemaker-mediated tachycardia (PMT) which cannot be controlled by reprogramming selective parameter values. In DDD, DDI, and AAI modes, atrial pacing may be ineffective in the presence of chronic atrial fibrillation or flutter or an atrium that does not respond to electrical stimulation. In addition, presence of clinically significant conduction disturbances may contraindicate the use of atrial pacing.

V. WARNINGS

- The use of non–CPI lead systems may cause potential adverse consequences such as undersensing cardiac activity and failure to deliver necessary therapy.
- Read this manual thoroughly before implanting the pulse generator to avoid damage to the AICD system. Such damage can result in injury to or death of the patient.
- Electrically isolate the patient from potentially hazardous leakage current to prevent inadvertent arrhythmia induction.
- Always have sterile external and internal defibrillator paddles or an equivalent (eg, R2 pads) immediately available during conversion testing. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death.
- Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

VI. PRECAUTIONS

Sterilization, Storage, and Handling

- Do not resterilize the device or the accessories packaged with it because CPI cannot ensure that resterilization is effective.
- Do not use the device if the packaging is wet, punctured, opened, or damaged because the integrity of the sterile packaging may be affected. Return the device to CPI.
- Store the device between 0-50°C (32-122°F) because temperatures outside this range could damage the device.
- Allow the device to reach room temperature before programming or implanting the device

because temperature extremes may affect initial device function.

- Store the pulse generator in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid device damage. Do not implant the pulse generator after the USE BEFORE date (which appears on the device packaging) has passed because this date reflects a reasonable shelf life.

Lead Evaluation and Lead Connection

- Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.
- Do not suture directly over the lead body as this may cause structural damage. Use the lead stabilizer to secure the lead lateral to the venous entry site.
- Tighten the setscrews onto the electrode rings of the rate sensing/pacing lead. Do not tighten the setscrews onto the silicone rubber insulation, because this may damage the lead.
- Never change the shock waveform polarity by mechanically switching the lead anodes and cathodes in the pulse generator header—use the programmable POLARITY feature. Device damage or nonconversion of the arrhythmia post–operatively may result if polarity is switched mechanically.
- Never implant the device with a lead system that has less than 15 W total lead impedance. Device damage may result. If a defibrillating lead impedance is less than 20 W, reposition the defibrillating leads to allow a greater distance between the shocking leads.

Programming

- Use only a CPI Programmer/Recorder/Monitor (PRM) and the Model 2833 Software Application to communicate with the VENTAK AV pulse generator.
- Electrical interference or "noise" from devices such as electrosurgical and monitoring equipment may cause improper interrogation or programming of the device. In the presence of such interference, move the programmer away from electrical devices and ensure that the wand cord and cables are not crossing one another.
- Do not leave the device programmed in STAT PACE settings, these settings may significantly reduce the lifetime of the device due to the high output.
- Do not perform P/R wave amplitude testing on patients with very low or no intrinsic ventricular rate because the device does not pace during this test. To determine a patient's intrinsic rate, reduce the LRL until intrinsic activity occurs.
- Select A for the atrial chamber (nominally set on V [ventricle]) before inducing atrial arrhythmias, to avoid inducing a ventricular arrhythmia.
- Ensure that the ATR/VTR FALLBACK LRL is programmed back to the normal and post–shock pacing if the ATR/VTR FALLBACK LRL value was changed during EP testing.
- Ensure that the pulse generator's TACHY MODE is OFF when not in use, before handling it, and before using electrosurgery to avoid inadvertent therapy.
- Verify with a conversion test that the patient's tachyarrhythmias can be detected and terminated by the AICD system if the patient's status has changed or parameters have been reprogrammed.
- Following any sensing range adjustment or any modification of the sensing lead, always verify appropriate sensing for bradycardia pacing and tachycardia detection.
- Make sure the PRM disk drive light is off before removing the patient data disk from the disk drive. Removing the disk while the drive heads are engaged can damage the disk and/or the drive.

Follow–up Testing

- Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post–implant device testing should the patient require external rescue.

- Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in nonconversion of the arrhythmia post–operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post–operatively.

Pulse Generator Disposal

- Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.
- Program the pulse generator TACHY MODE to OFF, disable the magnet feature, and disable the BEEP WHEN ERI IS REACHED beeper before explanting, cleaning, or shipping the device to prevent unwanted shocks, overwriting of important therapy history data, and audible tones.

Hazards Due to the Environment and Medical Therapy

Hospital and Medical Environments

- Do not use internal defibrillation paddles unless the pulse generator is disconnected from the leads because it may shunt energy causing injury to the patient, and may damage the pulse generator.
- Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator: position the defibrillation paddles as far from the pulse generator as possible, position the defibrillation paddles perpendicular to the implanted pulse generator-lead system, and set energy output of defibrillation equipment as low as clinically acceptable.
- Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. To verify proper function: interrogate the device, perform a capacitor re–formation, verify battery status, check the shock counters, and ensure that programmable parameters did not change.
- Do not use electrosurgery devices until the pulse generator is deactivated. If active, the pulse generator may deliver an inappropriate shock to the patient. Remember to reactivate the pulse generator after turning off the electrosurgery equipment.
- Do not subject a patient with an activated implanted pulse generator to diathermy since diathermy may damage the pulse generator.
- Shield the pulse generator during ionizing radiation exposure and do not project the radiation port directly at the device. Ionizing radiation (such as radioactive cobalt, linear accelerators, and betatrons) may damage the pulse generator operation, particularly at high doses. Always evaluate the pulse generator's operation after exposure to radiation.
- Lithotripsy may damage the pulse generator. If lithotripsy must be used, avoid focusing near the pulse generator site.

Home and Occupational Environment

- Advise patients to avoid sources of EMI (electromagnetic interference) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of electromagnetic sources that could interfere with normal device operation include:
  —Electrical power sources
  —Arc welding equipment and robotic jacks
  —Electrical smelting furnaces

—Large RF transmitters such as RADAR
—Therapeutic diathermy equipment
—Radio transmitters, including those used to control toys
—Electronic surveillance devices (anti–theft devices)
—Alternator on a car that is running

Cellular Phones

- Recent studies have indicated there may be a potential interaction between cellular phones and implantable defibrillator operation. Potential effects may be due to either the radio frequency signal or the magnet within the phone and could include inhibition or delivery of additional therapies when the phone is in close proximity (within 6 inches [15 cm]) to the pulse generator. Simply moving the phone away from the implanted device will return it to its previous state of operation. Because of the great variety of cellular phones and the wide variances in patient physiology, an absolute recommendation to cover all patients cannot be made. The following information provides a general guideline to patients having an implanted pulse generator who desire to operate a cellular phone. It is important to note that any effect resulting from an interaction between cellular phones and implanted pulse generators is temporary.

—Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices as some phones emit signals when they are turned on but not in use (ie, in the listen or standby mode). Storing the phone in a location opposite the side of implant is recommended.

—Maintain a minimum separation of 6 inches (15 cm) between a handheld personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to handheld models. For phones transmitting above 3 watts, a minimum separation of 12 inches (30 cm) between the antenna and the implanted device is advised.

Magnetic Sources

- Advise patients to avoid equipment or situations where they would be exposed to strong (>10 gauss or 1 mTesla) magnetic fields since the pulse generator mode could change. Examples of magnetic sources that could interfere with normal pulse generator operation include:

—Industrial transformers
—Industrial motors
—Magnetic resonance imaging (MRI) devices
—Large stereo speakers
—Telephone receivers if held within 0.5 inch (1.27 cm) of the pulse generator
—Magnetic wands such as those used for airport security and in the game "Bingo"

To prevent mode change in the presence of magnets, the CHANGE TACHY MODE WITH MAGNET feature may be programmed OFF.

VII. ADVERSE EVENTS

Table 2 below reports complications and observations on a per patient and a per patient-year basis. The VENTAK AV Implant Study involved 69 devices implanted in 69 patients with a cumulative implant duration of 149 months, mean implant duration = 2.2 [range 0.4 to 3.1] months. Adverse events (AEs) reported from this clinical trial included 8 complications and 48 observations. There was one patient death which was judged unrelated to the AICD.

Table 2. VENTAK AV Implant Study--Complications and Observations (n=69 patients)

	# pts with AEs	% of pts with	# of AEs[1]	AEs pt-yrs
Complications[2, 3] (total)	**8**	**10%**	**8**	**1**
Lead Displacement	3	4%	3	0.3
Lead insulation	1	1%	1	0.1
Brady undersensing, atrial	1	1%	1	0.1
Hematoma	1	1%	1	0.1
Arrhythmia nonconversion VF	1	1%	1	0.1
Migration of device	1	1%	1	0.1
Observations[4] (total)	**18***	**26%**	**32**	**3**
Programmer, disk or disk drive, general operation, user interface[5]	6	9%	6	0.5
Brady undersensing, oversensing	3	4%	4	0.3
ICD oversensing, myopotential	3	4%	3	0.2
Lead connector, tip	2	3%	2	0.2
Setscrew or header	2	3%	3	0.2
Change in arrhythmia	2	3%	2	0.2
Clinically inappropriate tachy	4	6%	4	0.3
Arrhythmia nonconversion VT	2	3%	2	0.2
Elevated pacing threshold	2	3%	2	0.2
Lead displacement	1	1%	1	0.1
Lead placement	1	1%	1	0.1
Impedance measurement	1	1%	1	0.1
Real-time pace/sense electrogram	1	1%	1	0.1

1. AEs = Adverse Effects
2. A complication is defined as a clinical event that results in invasive intervention, injury, or death (e.g., surgical interventions).
3. Fifteen complications involving high pace/sense lead impedance and rising pacing thresholds, typically at the 3-month follow-up visit, were excluded from this tabulation. The cause of the complications were traced to the pulse generator lead port connectors and has been corrected.
4. An observation is defined as a clinical event that does not result in invasive intervention, injury, or death.
5. Sixteen observations, mostly involving telemetry sensitivity, were excluded since the causes of the

observations were corrected in the PRM software.
*Patients may have had multiple observations, therefore, the total is representative of the number of unique patients.

Possible Adverse Events
Based on the literature and AICD implant experience, the following alphabetical list includes possible adverse events associated with implantation of an AICD system: Acceleration of arrhythmias • Air embolism • Bleeding • Chronic nerve damage • Erosion • Excessive fibrotic tissue growth • Extrusion • Fluid accumulation • Formation of hematomas or cysts • Inappropriate shocks • Infection • Keloid formation • Lead abrasion • Lead discontinuity • Lead migration/ dislodgement • Myocardial damage • Pneumothorax • Shunting current or insulating myocardium during defibrillation with internal or external paddles • Potential mortality due to inability to defibrillate or pace • Thromboemboli • Venous occlusion • Venous or cardiac perforation. Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychologic intolerance to an AICD system that may include the following: Dependency • Depression • Fear of premature battery depletion • Fear of shocking while conscious • Fear that shocking capability may be lost • Imagined shocking.

VIII. ALTERNATIVE PRACTICES AND PROCEDURES

Alternative therapies for the treatment of life-threatening ventricular arrhythmias, as deemed appropriate by the physician based upon electrophysiology (EP) testing and other diagnostic evaluation, include the use of antiarrhythmic medication, electrical ablation and cardiac surgery, electronic devices including pacemakers and other commercially available implantable defibrillators, or a combination thereof.

IX. MARKETING HISTORY

Since August 1996, the VENTAK AV System is commercially available in the following countries: the European Economic Area, Canada, Israel, Columbia, Turkey, and the Czech Republic. On February 3, 1997, CPI withdrew the VENTAK AV from commercial distribution after ten patients, out of approximately 200 implants, exhibited an abnormal increase in pacing impedance typically at their three month follow-up visit. CPI traced the issue to the pulse generator lead port and corrected it with a lead port design identical to commercially available VENTAK AICD devices. On April 11, 1997, CPI resumed commercial distribution of the VENTAK AV. Since resuming commercial distribution with the corrected design, approximately 300 VENTAK AV pulse generators have been implanted outside the United States as of May 22, 1997.

X. SUMMARY OF STUDIES

A. Non-clinical Laboratory Studies

The nonclinical laboratory testing consisted of bench testing (i.e., components, subassemblies, device system/software tests) biocompatibility, and animal studies. These studies were conducted prior to initiation of the clinical studies.

1. Component and Assemblies Tests

VENTAK AV components that were common to and used in the same functional way as other CPI commercially available pulse generators applications were not requalified for the VENTAK AV applications. Previously qualified components include such items as transistors, diodes, resistors, capacitors, and the high power output module. The pulse generator power source is two 3.2V solid-state lithium-iodine batteries manufactured by Wilson Greatbatch Ltd. The batteries were subjected to environmental, mechanical, and electrical stresses to demonstrate their ability to meet design specification requirements. Other new components (such as carriers; electrolytic capacitors, inductor, transformer flex circuit, telemetry coil, analog and digital hybrids, etc.) were subjected to various qualification tests. These tests included electrical tests, operating life tests, temperature cycle tests, visual inspections, dimensional inspections, solderability tests, hermeticity test, residual gas analysis, mechanical and material tests, humidity tests, solvent resistance, etc. Hybrid circuit assemblies were subjected to a series of operating life, temperature, process and environmental stress tests. The high power module and miscellaneous leadless chip carrier were also subjected to environmental stress including operating life test. All of the components and assemblies were considered qualified for use in implantable pulse generator applications.

2. Device Design and System Tests

Device design and system compatibility involved verification and validation of the VENTAK AV system: functionality testing; simulated use testing; and safety testing and analysis.

The functionality testing of VENTAK AV pulse generator and software application included the following: Battery Longevity Test, Electromagnetic Interference (EMI) Evaluation, Electronic Design Verification Test (DVT), Mechanical DVT, Pulse Generator Software DVT, and Model 2833 Software Application DVT.

Battery Longevity Test. Voltage and current measurements were taken throughout the battery rundown, so as to determine the effective capacity in the VENTAK AV application. An accelerated battery discharge was also achieved by allowing the device to periodically charge and deliver maximum energy shocks. Six different flex assemblies and six sets of batteries were used to introduce a representation of manufacturing variation to the test. Results of the tests determined that the battery capacity available between ERI (elective replacement indicator) and EOL (end-of-life) is more than adequate to support the capacity required for 10 maximum energy shocks and 3 months of 100% DDD pacing (108.4 mA-Hr mean) as required by the device specification.

Electromagnetic Compatibility (EMC) Evaluation. Three VENTAK AV devices were subjected to Radiated and Conducted electromagnetic interference (EMI), Electrical Hazards and Magnetic Fields based on the AAMI (Association for the Advancement Medical Instrumentation) August 1975 draft Pacemaker Standard and the CENELEC draft standard for EMI testing (DIN VDE 0750). The tests evaluated pulse generator's performance when subjected to the following: (1) Radiated radio frequency, pulse and continuous wave at up to 200 V/m field strength, (27, 72, 450, 900, 2450, and 3100 MHZ), (2) Conducted frequency from 16.6 Hz to 50 MHZ as defined in the Draft CENELEC Pacing System standard (3) High voltage defibrillation shock (850V peak), (4) Exposure to electrostatic discharge pulses (2000V from case to lead barrel), and (5) Exposure to static magnetic fields up to 10 mT (the reed switch is activated/deactivated when the field is maintained at >0.5mT for longer than 30 seconds). CPI reported that there were no instances of memory errors, parameter changes, reset conditions or damage from any test. All three devices showed the expected reversion mode in the presence of conducted signals of sufficient amplitude and frequency. Two devices showed susceptibility to pulsed RF at 27MHz and one device at 72MHz.

Electronic Design Verification Test. Test were performed on five devices to verify that the electrical requirements of the VENTAK AV pulse generator (PG) electronics met the device electrical specifications. The tests were performed on four different stages of PG assembly: (1) the welded PG assembly, (2) the PG assembly with external battery connections, (3) the flex assembly, and (4) the sytem board. Tests were conducted in the main functional areas: rate and electrogram sensing, pacing output characteristics, shock output characteristics, telemetry operation, therapy history time accuracy, fault detection, audio tone generation, magnet detection, and battery management.

Mechanical Design Verification Test. Samples of VENTAK AV pulse generators and assemblies were subjected to a battery of mechanical tests to verify that the devices met the mechanical design specifications. Testing was performed on devices which were exposed to a complete representative manufacturing process, including three sterilization cycles. Tests were conducted in the main functional areas: mechanical requirements, environmental tests, and package and shipping tests. Such tests included internal atmosphere and hermeticity, connector assembly lead and adapter compatibility, thermal shock and cycling, vibration, etc.

Pulse Generator Software Design Verification Test. Formal design verification testing of the software incorporated in the VENTAK AV pulse generator encompassed two different areas: the Flash EPROM and the Read-Only Memory on the chip (microcontrol). Using an automated test system, the testing verified the proper operation and interaction of the various tasks to be executed by the software (according to the test requirements specification) to ensure proper function, timing, and data exchange (e.g., hardware/software interface, battery requirements, cardioversion test requirements, detection rest requirements, etc.).

Model 2833 Software Application Design Verification Test. Formal design verification testing of the Model 2833 Programmer Software Application was conducted with either a full VENTAK AV system including a VENTAK AV pulse generator and a Model 2950 or 2901 PRM with the Model 2909 Multiple Application Utility (MAU) and Model 2833 Software Application installed on it, or the same system with a pulse generator simulator replacing the VENTAK AV pulse generator. The following is a list of some of the software features and tasks that were evaluated for their conformance with specifications: display, keypad , printer, telemetry, disk and control functions. CPI reported no anomalies relevant to safety or effectiveness.

Simulated use testing included the following: System Features Tests, an Arrhythmia Scenario Evaluation Test, a VENTAK AV System (pace/sense) Acute Device Study, a Field Clinical Engineer Simulated Use Test, and a GLP animal study (Section C below).

System Features Tests. System features tests was conducted to exercise major features of the VENTAK AV system. Each test demonstrated the functionality of a given feature and verified that the programmer has properly loaded parameters into the pulse generator. Feature groups tested include device family, programmer support, lead support, tachy modes, tachyarrhythmia detection, tachyarrhythmia therapy, bradycardia modes, bradycardia therapy, diagnostics, and faults/error handling.

Arrhythmia Scenario Evaluation Test. This test, also referred to as Human Arrhythmia Tape Test, was conducted to evaluate the performance of the arrhythmia detection algorithm in the VENTAK AV pulse generator using pre-recorded actual human heart signals. The tests were designed to verify that the VENTAK AV detects and delivers therapy in response to electrically treatable arrhythmias which fulfill the detection criteria, and does not detect and deliver therapy to those signals which do not fulfill the criteria. Test input data included the following waveforms: (1) Non-treatable electrograms for the VENTAK AV programmed as a ventricle only device, (2) Monomorphic electrograms for the VENTAK AV programmed as a ventricle only device, (3) Polymorphic ventricular tachycardia (VT) and ventricular fibrillation (VF) electrograms for the VENTAK AV programmed as a ventricle only device, and (4) Electrograms from both heart chambers for the VENTAK AV programmed as a dual chamber device. These rhythms included: normal sinus, atrial fibrillation/flutter, sinus tachycardia, ventricular fibrillation, and ventricular tachycardia. Detection and redection times were compared with the commercially available VENTAK MINI II AICD [PMA P910077/S12]. There was no significant difference in the detection or redection time between the VENTAK AV and the VENTAK MINI II except for one test where the initial detection time for the VENTAK MINI II was significantly longer (4.6 sec. for the VENTAK MINI II compared to 3.2 sec. for the VENTAK AV).

Acute Study Device Pace/Sense Study. A non-significant risk pace/sense study using VENTAK AV Acute Study Device (AVASD) was conducted. The AVASD is an external research tool which evaluated the performance characteristics of the VENTAK AV pulse generator sense amplifiers in human subjects. The acute study, which was conducted on 13 patients, obtained data on amplifier response (digital automatic gain control circuitry) to various clinical arrhythmias in order to optimize device response to cardiac activity. The study concluded that the AVASD amplifiers sensed intracardiac activity appropriately in both atrial and ventricular applications in an operating room environment.

Field Clinical Engineer Simulated Use Test. From a field user perspective, CPI field clinical engineers evaluated the performance of the VENTAK AV system and verified the Physician's System Manual and the Model 2833 Software Application Installation Kit Manual. Clinical scenarios were simulated using the pulse generator, programmer, software and a cardiac signal simulation.

The safety testing and analysis of the VENTAK AV system included hazards analysis, failure modes and effects criticality analysis (FMECA) and reliability prediction. The reliability prediction was performed in accordance with the "Parts Stress Analysis Prediction" procedure in MIL-HDBK-217F resulting in an expected failure level of 2.079 failures per million hours.

B. Biocompatibility

The biocompatibility of the tissue contacting materials used in the VENTAK AV AICD System has been established in previous PMA applications (P890061 and P910077). These materials include: polyurethane, titanium, and silicone rubber which are all currently used in CPI's commercially available AICD devices. There were no new materials or processes introduced with the VENTAK AV that would affect new issues of biocompatibility.

C. Animal Studies

CPI conducted an animal study to demonstrate mechanical and electrical system compatibility of the VENTAK AV AICD system *in-vivo* in an operating room environment using a porcine model. This study was done in compliance with Good Laboratory Practice (GLP) regulations (21 CFR §58). The study verified that the VENTAK AV system demonstrated proper mechanical and electrical system compatibility in an operating room environment using a porcine model.

D. Clinical Studies

Two clinical studies were conducted to evaluate safety and effectiveness of the VENTAK AV AICD System: (1) an acute paired study known as the VENTAK AV Acute Tachy Study, and (2) an observational study known as the VENTAK AV Implant Study. The VENTAK AV Acute Tachy Study was conducted under an approved investigational device exemption (IDE) application, G960109. The VENTAK AV AICD was compared to a commercially available ICD (VENTAK MINI AICD) in an acute (nonimplant) paired study of 33 patients and an observational study of 69 patients implanted with the VENTAK AV device.

1. Acute Study

The purpose of the acute study was to demonstrate the performance of the VENTAK AV system in detecting and treating ventricular arrhythmias, and to determine if post-shock pacing and sensing are comparable to the VENTAK MINI system. A total of 33 patients were tested in 2 U.S. centers and 4 centers outside the U.S from May 28, 1996 through November 22, 1996.

Patients studied: The patients (27 Males and 6 Females) had a mean age of 59 (range 14 to 86) years and a left ventricular ejection fraction of 40% (range 13% to 78%). Most (79%) presented with coronary artery disease or ischemic cardiomyopathy and about one-third (39%) presented with monomorphic ventricular tachycardia (MVT) as their primary arrhythmia.

Objectives: The primary endpoint was VF detection time for induced episodes. Secondary endpoints compared rates of appropriate tachyarrhythmia therapy decision and rates of appropriate post-shock bradycardia pacing and sensing.

Methods and Statistics: The acute study was done in the operating room or electrophysiology laboratory without device implantation. A 1:1 randomization scheme by center was used to assign which device was used for the first test episode; each patient served as his/her own control. The VENTAK AV and VENTAK MINI were utilized to perform arrhythmia detection testing to demonstrate appropriate detection of VF in the presence of high-rate pacing. In addition, the VENTAK AV was utilized to evaluate VF detection in the presence of atrial fibrillation. The sample size estimate was determined by the statistical requirements of the primary endpoint of the study. A minimum detection time of 1 second was chosen to compare the event detection time between the study and control devices. Estimates for variability for VF detection time were based on the published results from Callans, et al. (Callans, Swarna, Schwartzman. "Postshock Sensing Performance in Transvenous Defibrillation Lead System." Journal of Cardiovascular Electrophysiology, Vol. 6, pp 604-612, August 1995.) To detect a difference of 1 second in VF detection time, with a population standard deviation of 1.5 seconds, a sample size of 22 patients is required; a total of 33 patients were enrolled in the study to more fully evaluate the secondary endpoints.

Results: For the 33 patients treated with the VENTAK AV, appropriate therapy was delivered in 100% (62 of 62) [95% confidence interval 94% to 100%] of the tachyarrhythmia episodes, appropriate post-shock bradycardia pacing was delivered in 100% (53 of 53) [93%to 100%] of the events, and appropriate post-shock bradycardia sensing was delivered in 93.3% (55 of 59) [84% to 98%] of the events. Ventricular fibrillation (VF) was detected in the presence of high-rate pacing in 100% (33 of 33) [88% to 100%] of the events. The mean (95% confidence interval) VF detection time was 2.0 [1.8 to 2.2] sec. There were no patient deaths or other complications reported in the acute study for either device.

Gender Bias Analysis: Twenty-seven males (81.8%) and six females (18.2%) were studied in this investigation. This proportion is not statistically different than the gender distribution (80.7% males, 19.3% females) for commercially available CPI AICDs implanted worldwide since 1982. No statistical differences were found between males and females tested with the VENTAK AV with respect to age, Left Ventricular Ejection Fraction (LVEF), New York Heart Association (NYHA) Classification, or primary arrhythmia. With respect to VF detection times, no statistical differences exist between males and females (p= 0.37). No complications occurred among males or females tested in this study. The results between males and females show that safety and effectiveness do not differ with respect to gender.

2. Implant Study

The purpose of the implant study was to confirm that the VENTAK AV could sense, detect, and deliver ventricular tachyarrhythmia therapy. Seventy patients were enrolled in 17 centers outside the U.S. The VENTAK AV AICD was implanted in 69 patients (one patient was not implanted due to difficult lead placement) from September 2, 1996 through October 31, 1996.

Patients Studied. The patients (56 Males and 13 Females) had a mean age of 60 (range 12 to 77) years and a left ventricular ejection fraction of 40% (10% to 81%). Most (64%) presented with coronary artery disease or ischemic cardiomyopathy and 46% presented with monomorphic ventricular tachycardia (MVT) as their primary arrhythmia.

Objective: The primary endpoint was VF detection time for induced episodes.

Methods and Statistics. The sample size and statistical power consideration was calculated to enable comparison of the VENTAK AV Acute Tachyarrhythmia Study (IDE G960109) which measured VF detection times. Based on this calculation the required sample size for the VENTAK AV Implant Study is 32 patients per group. For analysis of the primary endpoint, VF Detection time, the VENTAK AV Acute Tachyarrhythmia Study (non-implanted VENTAK MINI control group) consisted of 33 patients, and the VENTAK AV Implant Study (implanted VENTAK AV group) consisted of 36 patients. The VENTAK AV Implant Study enrolled additional patients, for a total of 69 patients, to collect additional observation, complication, and spontaneous episode data for an implanted VENTAK AV.

Results. The mean implant duration was 2.2 (range 0.4 to 3.1) months with a cumulative implant duration of 149 months. A total of 331 episodes of VF were treated including spontaneous (N=40) and induced (n=291). Two patients had episodes that were not converted by the device. One patient had two MVT episodes that were device nonconversions. The second patient had episodes that were not converted by the device or external defibrillation and expired. The patient death was judged unrelated to the device. All other spontaneous episodes of ventricular arrhythmias were converted by device therapy. Results were compared to previous experience with the VENTAK MINI (nonconcurrent historical control). A summary of the study results is listed in Table 3 below.

Gender Bias Analysis. Fifty-six males (81.2%) and thirteen females (18.8%) were studied in this investigation. This proportion is not statistically different than the gender distribution (80.7% males, 19.3% females) for commercially available CPI AICDs implanted worldwide since 1982. The results between males and females show that safety and effectiveness do not differ with respect to gender.

Table 3. VENTAK AV Implant Study Results
All patients implanted, N=69, 149 implant months

Effectiveness Measure	VENTAK AV Mean ± SD [95% CI*]	VENTAK MINI Mean ± SD [95% CI*]	Difference [95% CI]
Defibrillation Threshold (J)	9.1 ± 4.9 [7.3, 10.9]	NA	NA
VF Detection Time (sec)	2.2 ± 0.53 [2.0, 2.4]	1.9 + 0.64 [1.7, 2.1]	0.35 [0.12 to 0.58]
Safety Measure	**num/denomin (%)**		
Operative Mortality (%)	1/69 (1.3%) [0%, 8%]		
Conversion Efficacy (%)	322/331 (97%) [95%, 99%]		

* CI = Confidence Interval by Exact Binomial

XI. CONCLUSIONS DRAWN FROM STUDIES

In vitro test results provide reasonable assurance that the VENTAK AV is reliable and biocompatible. The results of *in vivo* animal study, *in vitro* acute clinical studies, and implants outside the U.S. demonstrated the proper operation of the device and provide reasonable assurance that the VENTAK AV is safe and effective when it is used as indicated in the labeling.

XII. FDA DECISION

In accordance with the provisions of section 515(c) (2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

FDA conducted an inspection of CPI's manufacturing facilities (St. Paul, MN) and determined that the manufacturer was in compliance with the Device Good Manufacturing Practices Regulation (21 CFR part 820).

CPI notified FDA about reports of VENTAK AV patients from outside the United States who exhibited high pacing lead impedance (and potential loss of capture), typically at the three-month follow-up visit. The clinical events resulted in explants or reprogramming the device from DDD to VVI. CPI immediately began a crossfunctional investigation to identify the root cause. Device implants were stopped. The shipment of the VENTAK AV was also halted on February 1, 1997 and CPI issued a recall letter on February 3, 1997. CPI's investigation found that the root cause of this complication was traced to the pulse generator lead port connectors.

CPI has corrected the problem by reworking the VENTAK AV header to replace the 3.2 mm IS-1 pace/sense lead connector block with the same connector block design used in existing commercially available CPI AICDs. As of June 26, 1997, 43 VENTAK AV pulse generators remain implanted worldwide in the study population of 69 patients, 41 with the original device and 2 with replacement VENTAK AV. There have been a total of 28 explants (3 deaths and 21 devices due to complications involving high pace/sense lead impedance and rising pacing thresholds). The three deaths were judged unrelated to the AICD.

CPI resumed commercial distribution of the VENTAK AV with the corrected design on April 11, 1997. There were no new reports of patients exhibiting high pacing impedance with the corrected design.

On June 4, 1997, CPI submitted an amendment to the application providing the information and correcting the deficiencies required by FDA in a February 26, 1997 *'Not Approvable'* letter. On July 15 and July 17, 1997, CPI submitted amendments to the application providing additional information required by FDA in a July 14, 1997 *'Approvable'* letter.

FDA approved the PMA on July 18, 1997. FDA approval is subject to the applicant's compliance with the "Conditions of Approval for Implantable Pacemakers and Programmers" (Attachment A), and the conditions that the sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

XIII. APPROVAL SPECIFICATION

CPI will conduct a post-market surveillance study of the VENTAK AV as required by the 1990 Safe Medical Device Act.

353606

CPI®

PHYSICIAN'S SYSTEM MANUA

VENTAK® AV 1810/1815

Automatic Implantable Cardioverter Defibrillator

353606-002A
VENTAK AV US
7/2/97

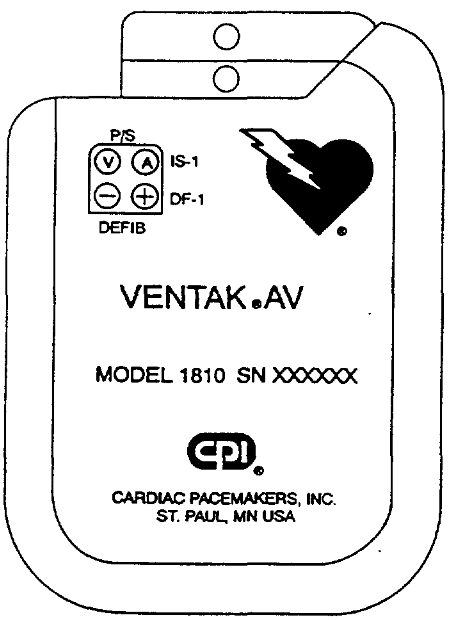
NOMINAL MECHANICAL SPECIFICATIONS

Characteristic	Model 1810 VENTAK AV	Model 1815 VENTAK AV
Size	6.4 cm wide 8.5 cm high 1.7 cm deep	6.4 cm wide 9.6 cm high 1.7 cm deep
Volume	79 cc	85 cc
Mass (weight)	150 g	158 g
Defibrillating lead ports†	Accept CPI 3.2-mm DF-1* defibrillating leads (defibrillating lead ports will not accept 3.2-mm in-line bipolar leads)	Accept CPI 6.1-mm leads
Ventricular pace/sense lead port(s)†	Accepts CPI 3.2-mm IS-1* bipolar lead	Accept CPI 4.75-mm leads
Atrial pace/sense lead port	Accepts CPI 3.2-mm IS-1* bipolar lead	Accepts CPI 3.2-mm IS-1* bipolar lead

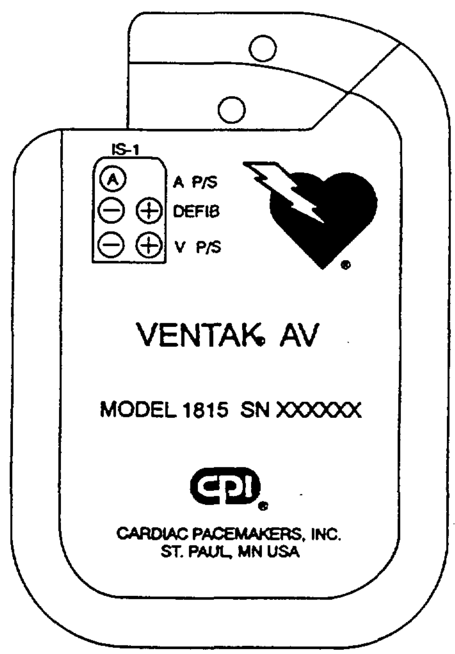
† For lead compatibility information, refer to Appendix E and the non-CPI lead system warning on page 2.
* DF-1 refers to the international standard ISO 11318:1993. IS-1 refers to the international standard ISO 5841.3:1992.

VENTAK AV Models 1810 and 1815

Case material	Hermetically sealed titanium
Header material	Implantation-grade polymer
Power supply	Two lithium-silver vanadium oxide cells



Device with 3.2-mm header



Device with 6.1/4.75-mm header

CONTENTS

ABOUT THIS MANUAL

This physician's system manual contains a description of the VENTAK AV AICD pulse generator, as well as the Model 2833 Software Application and the CPI Programmer/Recorder/Monitor (PRM) system used to program the pulse generator.

The Table of Contents provides a view of the logical flow of subjects. The Index at the back of the manual provides an alphabetical listing of subjects in the manual, allowing it to be used as an easy-to-use reference document.

Chapter 2 should be read to familiarize yourself with the software and the terminology. The terminology introduced in this chapter will be used throughout the manual.

Chapters 3, 4, and 5 contain information about detection and therapy functions. The early part of each chapter describes the pulse generator functions in detail, and the latter part of the chapter explains how to access the functions using the PRM system and software application. The software explanation typically includes a list of steps required to interact with the software. This format allows the information to be read with continuity or as a reference to pulse generator and system functions.

The appendices provide topics that expand on pulse generator operation, such as lead compatibility, external cable connections, and pacemaker interaction. Appendix A contains a quick-reference list of programmable options for the pulse generator parameters.

Chapter 1

DEVICE DESCRIPTION

The CPI VENTAK® AV™ AICD™ is a multiprogrammable, automatic, implantable cardioverter defibrillator with bidirectional telemetry. As a multifunctional electrical device (defibrillator and dual-chamber pacemaker, DDD), it is designed to provide defibrillation therapy (biphasic and monophasic shocks) as well as antitachycardia pacing (ATP) and dual-chamber bradycardia therapy (atrial and ventricular pacing).

The pulse generator (Model 1810 or Model 1815), along with compatible commercially available pace/sense leads and cardioversion/defibrillation leads constitutes the implantable portion of the AICD system[1]. Also, the pulse generator case acts as a defibrillating electrode. The lead systems for the VENTAK AV AICD pulse generator are implanted using either transvenous or transthoracic techniques. The CPI Programmer/Recorder/Monitor (PRM), the Model 2833 Software Application, and an accessory telemetry wand constitutes the external portion of the AICD system.

Indications for Use

The VENTAK AV AICD system is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular tachyarrhythmias and who have experienced one of the following situations:

- Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia
- Recurrent, poorly tolerated sustained ventricular tachycardia (VT)
- Prior myocardial infarction, left ventricular ejection fraction of ≤ 35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic have not been studied.

NOTE: *The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.*

The VENTAK AV AICD pulse generator is not intended for use solely as a primary bradycardia support device.

Contraindications

Use of the VENTAK AV AICD pulse generator is contraindicated in:

- Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning
- Patients who have a unipolar pacemaker

NOTE: *If a separate pacemaker is desired, a dedicated bipolar pacemaker is recommended. Refer to Appendix B for information about required pacemaker/AICD interaction testing and procedures.*

DDD and VDD modes are contraindicated as follows:

- In patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which may trigger ventricular pacing
- In the presence of slow retrograde conduction that induces pacemaker-mediated tachycardia (PMT) which cannot be controlled by reprogramming selective parameter values

1. Refer to the Nominal Mechanical Specifications table in the inside front cover of the manual for the defibrillating and pace/sense lead port dimensions.

In DDD, DDI, and AAI modes, atrial pacing may be ineffective in the presence of chronic atrial fibrillation or flutter or an atrium that does not respond to electrical stimulation. In addition, presence of clinically significant conduction disturbances may contraindicate the use of atrial pacing.

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Warnings

- The use of non-CPI lead systems may cause potential adverse consequences such as undersensing cardiac activity and failure to deliver necessary therapy.
- Read this manual thoroughly before implanting the pulse generator to avoid damage to the AICD system. Such damage can result in injury to or death of the patient.
- Electrically isolate the patient from potentially hazardous leakage current to prevent inadvertent arrhythmia induction.
- Always have sterile external and internal defibrillator paddles or an equivalent (eg, R2 pads) immediately available during conversion testing. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death.
- Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

Precautions

Sterilization, Storage, and Handling

- Do not resterilize the device or the accessories packaged with it because CPI cannot ensure that resterilization is effective.
- Do not use the device if the packaging is wet, punctured, opened, or damaged because the integrity of the sterile packaging may be affected. Return the device to CPI.
- Store the device between 0–50°C (32–122°F) because temperatures outside this range could damage the device.
- Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.
- Store the pulse generator in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid device damage.
- Do not implant the pulse generator after the USE BEFORE date (which appears on the device packaging) has passed because this date reflects a reasonable shelf life.

Lead Evaluation and Lead Connection

- Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.
- Do not suture directly over the lead body as this may cause structural damage. Use the lead stabilizer to secure the lead lateral to the venous entry site. (Page 106)
- Tighten the setscrews onto the electrode rings of the rate sensing/pacing lead. Do not tighten the setscrews onto the silicone rubber insulation, because this may damage the lead.
- Never change the shock waveform polarity by mechanically switching the lead anodes and cathodes in the pulse generator header—use the programmable POLARITY feature. Device damage or nonconversion of the arrhythmia post-operatively may result if polarity is switched mechanically.
- Never implant the device with a lead system that has less than 15 Ω total lead impedance. Device damage may result. If a defibrillating lead impedance is less than 20 Ω, reposition the defibrillating leads to allow a greater distance between the shocking leads.

Programming

- Use only a CPI Programmer/Recorder/Monitor (PRM) and the Model 2833 Software Application to communicate with the VENTAK AV pulse generator.

- Electrical interference or "noise" from devices such as electrosurgical and monitoring equipment may cause improper interrogation or programming of the device. In the presence of such interference, move the programmer away from electrical devices and ensure that the wand cord and cables are not crossing one another.
- Do not leave the device programmed in STAT PACE settings, these settings may significantly reduce the lifetime of the device due to the high output.
- Do not perform P/R wave amplitude testing on patients with very low or no intrinsic ventricular rate because the device does not pace during this test. To determine a patient's intrinsic rate, reduce the LRL until intrinsic activity occurs.
- Select A for the atrial chamber (nominally set on V [ventricle]) before inducing atrial arrhythmias, to avoid inducing a ventricular arrhythmia.
- Ensure that the ATR/VTR FALLBACK LRL is programmed back to the normal and post-shock pacing if the ATR/VTR FALLBACK LRL value was changed during EP testing.
- Ensure that the pulse generator's TACHY MODE is OFF when not in use, before handling it, and before using electrosurgery to avoid inadvertent therapy.
- Verify with a conversion test that the patient's tachyarrhythmias can be detected and terminated by the AICD system if the patient's status has changed or parameters have been reprogrammed.
- Following any sensing range adjustment or any modification of the sensing lead, always verify appropriate sensing for bradycardia pacing and tachycardia detection.
- Make sure the PRM disk drive light is off before removing the patient data disk from the disk drive. Removing the disk while the drive heads are engaged can damage the disk and/or the drive.

Follow-up Testing

- Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.
- Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in nonconversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Pulse Generator Disposal[2]

- Be sure that the pulse generator is removed before cremation. Never incinerate a pulse generator, as it contains sealed chemical power cells and capacitors. and may explode
- Program the pulse generator TACHY MODE to OFF, disable the magnet feature, and disable the BEEP WHEN ERI IS REACHED beeper before explanting, cleaning, or shipping the device to prevent unwanted shocks, overwriting of important therapy history data, and audible tones.

Hazards Due to the Environment and Medical Therapy

Hospital and Medical Environments

- Do not use internal defibrillation paddles unless the pulse generator is disconnected from the leads because it may shunt energy causing injury to the patient, and may damage the pulse generator.
- Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator: position the defibrillation paddles as far from the pulse generator as possible, position the defibrillation paddles perpendicular to the implanted pulse generator–lead system, and set energy output of defibrillation equipment as low as clinically acceptable.

2. Refer to the Explantation section in Chapter 11.

- Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. To verify proper function: interrogate the device, perform a capacitor re-formation, verify battery status, check the shock counters, and ensure that programmable parameters did not change.

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- Do not use electrosurgery devices until the pulse generator is deactivated. If active, the pulse generator may deliver an inappropriate shock to the patient. Remember to reactivate the pulse generator after turning off the electrosurgery equipment.

- Do not subject a patient with an activated implanted pulse generator to diathermy since diathermy may damage the pulse generator.

- Shield the pulse generator during ionizing radiation exposure and do not project the radiation port directly at the device. Ionizing radiation (such as radioactive cobalt, linear accelerators, and betatrons) may damage the pulse generator operation, particularly at high doses. Always evaluate the pulse generator's operation after exposure to radiation.

- Lithotripsy may damage the pulse generator. If lithotripsy must be used, avoid focusing near the pulse generator site.

Home and Occupational Environment

- Advise patients to avoid sources of EMI (electromagnetic interference) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of electromagnetic sources that could interfere with normal device operation include:

  — Electrical power sources
  — Arc welding equipment and robotic jacks
  — Electrical smelting furnaces
  — Large RF transmitters such as RADAR
  — Therapeutic diathermy equipment
  — Radio transmitters, including those used to control toys
  — Electronic surveillance devices (anti-theft devices)
  — Alternator on a car that is running

Cellular Phones

- Recent studies have indicated there may be a potential interaction between cellular phones and implantable defibrillator operation. Potential effects may be due to either the radio frequency signal or the magnet within the phone and could include inhibition or delivery of additional therapies when the phone is in close proximity (within 6 inches [15 cm]) to the pulse generator. Simply moving the phone away from the implanted device will return it to its previous state of operation. Because of the great variety of cellular phones and the wide variances in patient physiology, an absolute recommendation to cover all patients cannot be made. The following information provides a general guideline to patients having an implanted pulse generator who desire to operate a cellular phone. It is important to note that any effect resulting from an interaction between cellular phones and implanted pulse generators is temporary.

  — Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices as some phones emit signals when they are turned on but not in use (ie, in the listen or standby mode). Storing the phone in a location opposite the side of implant is recommended.

  — Maintain a minimum separation of 6 inches (15 cm) between a handheld personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to handheld models. For phones transmitting above 3 watts, a minimum separation of 12 inches (30 cm) between the antenna and the implanted device is advised.

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Magnetic Sources[3]

- Advise patients to avoid equipment or situations where they would be exposed to strong (>10 gauss or 1 mTesla) magnetic fields since the pulse generator mode could change. Examples of magnetic sources that could interfere with normal pulse generator operation include:

  — Industrial transformers
  — Industrial motors
  — Magnetic resonance imaging (MRI) devices
  — Large stereo speakers
  — Telephone receivers if held within 0.5 inch (1.27 cm) of the pulse generator
  — Magnetic wands such as those used for airport security and in the game "Bingo"

  To prevent mode change in the presence of magnets, the CHANGE TACHY MODE WITH MAGNET feature may be programmed OFF.

Adverse Events

The VENTAK AV AICD system implant study involved 69 devices implanted in 69 patients with a cumulative implant duration of 149 months, mean implant duration = 2.2 [range 0.4 to 3.1] months. Adverse events (AEs) reported from this clinical trial included 8 complications and 48 observations. There was one patient death which was judged unrelated to the AICD.

Table 1. Adverse Events Reported in > 1 Patient/Group
All patient (N = 69), Number and % of patients, Number of events, and Events/patient year

	# pts with AEs (n = 69)	% of pts with AEs	# of AEs[1]	AE/pt-yrs (n = 13)
Complications[2, 3] (total)	**8**	**10%**	**8**	**1**
Lead displacement	3	4%	3	0.3
Lead insulation	1	1%	1	0.1
Brady undersensing, atrial	1	1%	1	0.1
Hematoma	1	1%	1	0.1
Arrhythmia nonconversion VF	1	1%	1	0.1
Migration of device	1	1%	1	0.1
Observations[4] (total)	**18***	**26%**	**32**	**3**
Programmer, disk or disk drive, general operation, user interface[5]	6	9%	6	0.5
Clinically inappropriate tachy therapy	4	6%	4	0.3
Brady undersensing, oversensing	3	4%	4	0.3
ICD oversensing, myopotential	3	4%	3	0.2
Lead connector, tip	2	3%	2	0.2
Setscrew or header	2	3%	3	0.2
Change in arrhythmia	2	3%	2	0.2
Arrhythmia nonconverson VT	2	3%	2	0.2
Elevated pacing threshold	2	3%	2	0.2
Lead displacement	1	1%	1	0.1

3. Refer to Chapter 9 for more magnet information.

Lead placement	1	1%	1	0.1
Impedance measurement	1	1%	1	0.1
Real-time pace/sense electrogram	1	1%	1	0.1

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1. AEs = Adverse Effects
2. A complication is defined as a clinical event that results in invasive intervention, injury, or death (eg, surgical interventions).
3. Fifteen complications involving high pace/sense lead impedance and rising pacing thresholds, typically at the 3-month follow-up visit, were excluded from this tabulation. The cause of complications was traced to the pulse generator lead port connectors and has been corrected.
4. An observation is defined as a clinical event that does not result in invasive intervention, injury, or death.
5. Sixteen observations, mostly involving telemetry sensitivity, were excluded since the causes of the observations were corrected in the PRM software.

* Patients may have had multiple observations, therefore, the total is representative of the number of unique patients.

Potential Adverse Events

Based on the literature and AICD implant experience, the following alphabetical list includes possible adverse events associated with implantation of an AICD system:

- Acceleration of arrhythmias
- Air embolism
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion
- Lead discontinuity
- Lead migration/dislodgement
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychologic intolerance to an AICD system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking

Clinical Summary

The VENTAK AV AICD was compared to a commercially available ICD (VENTAK MINI AICD) in an acute (nonimplant) paired study of 33 patients and an observational study of 69 patients implanted with the VENTAK AV device.

Acute Study

The purpose of the acute study was to demonstrate the performance of the VENTAK AV system in detecting and treating ventricular arrhythmias, and to determine if post-shock pacing and sensing are comparable to the VENTAK MINI system. A total of 33 patients were tested in 2 U.S. centers and 4 centers outside the U.S.

Patients studied: The patients (27 M / 6 F) had a mean age of 59 (range 14 to 86) years and a left ventricular ejection fraction of 40% (range 13% to 78%). Most (79%) presented with coronary artery disease or ischemic cardiomyopathy and about one-third (39%) presented with monomorphic ventricular tachycardia (MVT) as their primary arrhythmia.

Methods: The acute study was done in the operating room or electrophysiology laboratory without device implantation. The primary endpoint was VF detection time for induced episodes.

Results: For the 33 patients treated with the VENTAK AV, appropriate therapy was delivered in 100% (62 of 62) [95% confidence interval 94% to 100%] of the tachyarrhythmia episodes, appropriate post-shock bradycardia pacing was delivered in 100% (53 of 53) [93% to 100%] of the events, and appropriate post-shock bradycardia sensing was delivered in 93.3% (55 of 59) [84% to 98%] of the events. Ventricular fibrillation (VF) was detected in the presence of high-rate pacing in 100% (33 of 33) [89% to 100%] of the events. The mean (95% confidence interval) VF detection time was 2.0 [1.8 to 2.2] sec. There were no patient deaths or other complications reported in the acute study for either device.

Implant Study

The purpose of the implant study was to confirm that the VENTAK AV could sense, detect, and deliver ventricular tachyarrhythmia therapy. Seventy patients were enrolled in 17 centers outside the U.S. The VENTAK AV AICD was implanted in 69 patients (one patient was not implanted due to difficult lead placement).

Patients studied: The patients (56 M / 13 F) had a mean age of 60 (range 12 to 77) years and a left ventricular ejection fraction of 40% (10% to 81%). Most (64%) presented with coronary artery disease or ischemic cardiomyopathy and 46% presented with monomorphic ventricular tachycardia (MVT) as their primary arrhythmia.

Methods: The primary endpoint was VF detection time for induced episodes. Results were compared to previous experience with the VENTAK MINI (nonconcurrent historical control).

Results: The mean implant duration was 2.2 (range 0.4 to 3.1) months with a cumulative implant duration of 149 months. A total of 331 episodes of ventricular fibrillation (VF) were treated including spontaneous (n = 40) and induced (n = 291). Two patients had episodes that were not converted by the device. One patient had two MVT episodes that were device nonconversions. The second patient had episodes that were not converted by the device or external defibrillation, and expired. All other spontaneous episodes of ventricular arrhythmias were converted by device therapy. There was one patient death which was judged unrelated to the ICD.

Table 2. VENTAK AV Implant Study Results
All patients implanted, N = 69, 149 implant months

Effectiveness Measure	VENTAK AV Mean ± SD [95% CI*]	VENTAK MINI Mean ± SD [95% CI]	Difference [95% CI]
Defibrillation Threshold (J)	9.1 ± 4.9 [7.3, 10.9]	NA	NA
VF Detection Time (sec)	2.2 ± 0.53 [2.0, 2.4]	1.9 ± 0.64 [1.7, 2.1]	0.35 [0.12 to 0.58]
Safety Measure	**num/den (%)**		
Operative Mortality (%)	1/69 (1.3%) [0%, 8%]		
Conversion Efficacy (%)	322/331 (97%) [95%, 99%]		

* CI = Confidence Interval

Individualization of Treatment

- Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.
- Determine if the device and programmable options are appropriate for patients with drug-resistant supraventricular tachyarrhythmias (SVTs), because drug-resistant SVTs can initiate unwanted device therapy.

Patient Counseling Information

- The AICD pulse generator is subject to random component failure. Such failure could cause inappropriate shocks, induction of arrhythmias or inability to sense arrhythmias, and could lead to the patient's death.
- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's AICD system delivers a shock.
- Advise patients to contact their physician immediately if they hear tones coming from their device.
- A copy of the patient manual is packaged with each device for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with operation of the device. (For additional copies of the patient manual, contact the nearest CPI sales representative or contact CPI at the address on the back cover of this manual.

Evaluating Prospective AICD Pulse Generator Patients

The prospective patient's size and activity level should be evaluated to determine whether a pectoral or abdominal implant is suitable. It is strongly recommended that candidates for VENTAK AV AICD therapy have a complete cardiac evaluation including EP testing prior to device implant to gather electrophysiologic information, including the rates and classifications of all the patient's cardiac rhythms. When gathering this information, delineate all clinically significant ventricular and atrial arrhythmias, whether they occur spontaneously or during EP testing.

If the patient's condition permits, use exercise stress testing to do ~~obtain~~ the following ~~information:~~

- Determine the maximum rate of the patient's normal rhythm
- Identify any supraventricular tachyarrhythmias
- Identify exercise-induced tachyarrhythmias

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of pulse generator implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify pulse generator detection and conversion. The pulse generator also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affect the patient's normal cardiac rate or conduction can affect the rate of tachyarrhythmias and/or efficacy of therapy.

If another cardiac surgical procedure is performed prior to implanting the VENTAK AV AICD pulse generator, it may be preferable to implant the lead system at that time. This may prevent the need for an additional thoracic operation.

Device Features

By programming device parameters, the AICD pulse generator is able, for a given patient, to detect and treat ventricular tachycardia and ventricular fibrillation with a combination of antitachycardia pacing and monophasic or biphasic cardioversion/defibrillation shocks. Detection of the atrial rate is available using an atrial lead. The pulse generator also detects and treats bradycardia conditions with pacing pulses in both the atrium and ventricle. Pulse generator memory provides a record of patient data, therapy delivery counts, and a therapy history consisting of arrhythmia episode data, conversion attempt data, stored electrograms (EGM), and annotated P–P and R–R intervals present during and following a tachyarrhythmic episode. The pulse generator automatically re-forms its capacitors and provides diagnostic data for evaluating battery status, lead integrity, and pacing thresholds.

The total system allows the physician to noninvasively interact with the pulse generator as listed below.

- Interrogate and program the pulse generator's tachycardia and bradycardia detection and therapy parameters
- Deliver a maximum-output STAT SHOCK (29 J) with the STAT SHOCK command
- Deliver emergency VVI pacing with the STAT PACE command
- Divert therapy delivery
- Access the pulse generator memory to review therapy history and stored electrograms
- View real-time electrograms and event markers
- Induce, monitor, and terminate arrhythmias during electrophysiologic testing
- Program optional features such as magnet use and audible tones
- Review the pulse generator battery status
- Print reports and save patient information on disk

Factory Preset Parameters

The pulse generator's parameters are preset at factory nominal values. Appendix A provides a complete list of parameters, available programmable values, nominal values and tolerances.

The pulse generator is shipped in a power-saving STORAGE mode to extend its shelf life. All features are inactive except telemetry support (allowing interrogation, programming), real-time clock, commanded capacitor re-formation, and automatic 24-hour battery measurement. STAT SHOCK and STAT PACE commands also are available from the STORAGE mode. The device will leave the STORAGE mode when STAT SHOCK or STAT PACE is commanded or when the TACHY MODE is programmed to OFF, MONITOR ONLY or MONITOR + THERAPY. Programming other parameters will not affect the STORAGE mode. Once programmed out of the power-saving STORAGE mode, the programmer cannot return the pulse generator to that mode.

NOTE: *The rate-sensing circuits may take up to eight seconds to begin tracking the cardiac signal after leaving the power-saving STORAGE mode. Brady pacing is inhibited during this period. The device should always be programmed out of the power-saving STORAGE mode to the OFF mode before connection to the patient leads.*

X-ray Identifier

CPI pulse generators have an identifier that is visible on x-ray film (Figure 1). This provides noninvasive confirmation of manufacturer and model number. The identifier consists of the letters CPI to identify the manufacturer and the model number; eg, "CPI 1810" identifies the Model 1810 VENTAK AV pulse generator manufactured by Cardiac Pacemakers.

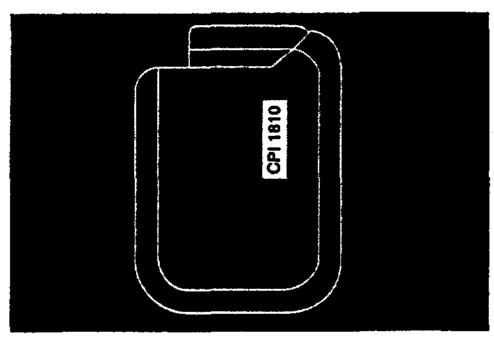

Figure 1. The pulse generator identifier is visible on x-ray as shown in this diagram.

Items Included

The following items are packaged with the VENTAK AV pulse generator:

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- One vial of sterile mineral oil
- One torque wrench
- One hex wrench
- Product literature
- One Model 6926 Patient Data Disk

NOTE: *Wrenches are intended for one-time use only and should not be resterilized or re-used.*

Opening Instructions

The sterile tray has a single sterile barrier on the outside tray; the inner clamshell tray is sterile. To open the clamshell, pry apart the tabbed edge. A diagram of the opening instructions is found inside the cover of the pulse generator shelf box.

Warranty Information

A limited warranty certificate for the pulse generator accompanies this manual. For additional copies, please contact: Guidant Corporation/Cardiac Pacemakers (CPI), 4100 Hamline Avenue North, St. Paul, MN 55112-5798. Telephone: 1-800-CARDIAC (1-800-227-3422).